SEP 20 2012

Owner/Manufacturer:	Owner Surefire Medical, Inc. 8601 Turnpike Dr. Suite 206 Westminster, CO 80031	Manufacturer Surefire Medical, Inc. 12415 SW136 Avenue Unit 3 Miami, FL 33186
Contact Person:	Mario Arbesu Director, Quality Assurance and Regulatory Affairs 305.378.2651	
Date of Summary Preparation:	16 July 2012	
Trade Name:	Surefire® High Flow Angiographic Catheter	
Common Name:	Intravascular Catheter	
Classification Name:	Intravascular Diagnostic Catheter	
Classification:	Class II	
Classification Regulation:	21 CRF Part 870.1200 - Diagnostic intravascular catheter.	
Product Code:	DQO	
Intended Use:	The Surefire® High Flow Angiographic Catheter is intended for use where angiographic diagnosis is indicated.	
Device Description:	The Surefire High Flow Angiographic Catheter (SAC) is used to facilitate advancement of the Surefire High Flow Microcatheter to the target vessel. The SAC is a single lumen, fixed length guide catheter with a Luer Lock Hub. It is compatible with standard 0.038" guide wires, Luer lock infusion syringes, and rotating hemostatic valves (RHVs). The angiographic catheter has an approximate length of 65 cm (usable length). A reinforced proximal section allows for ease of insertion and the barium sulfate filled extrusion provides clear fluoroscopic images of the shaft. A braided tungsten filled shaped tip provides visual feedback for the location of the guide catheter under fluoroscopy. The distal tip is rounded for atraumatic tracking. A shaped tip will assist to deliver the Surefire High Flow Angiographic Catheter to the desired target site. A peel-away Introducer is supplied with the SAC to insert the shaped tip into a catheter sheath introducer. The system is provided sterile (EO) for single patient use. The Angiographic Catheter is	

packaged in sealed sterile protective pouches and product boxes.

Principals of Operation/ Technology: The Surefire® High Flow Angiographic Catheter is operated manually.

Performance Testing & Verification Testing

- Kink Radius Testing
- Trackability Testing
- Pull Strength Testing
- High Pressure Injection Testing
- Infusion Agent Compatibility Testing
- Package Integrity (Pouch Bubble) Testing
- Device Corrosion Testing
- Visual and Dimensional Inspections
- Shape Retention Testing
- Particulate Testing
- Tensile Testing
- Torque Testing
- Shelf Life Testing

Biocompatibility Testing

- **Cytotoxicity** – Tested in accordance with ISO 10993-5
- **Sensitization** – Tested in accordance with ISO 10993-10
- **Intra-cutaneous irritation** – Tested in accordance with ISO 10993-10
- **Toxicity** – Tested in accordance with ISO 10993-11
- **Pyrogenicity** – Tested in accordance with USP General Chapter <151> Pyrogen Test recommended in ISO 10993-11
- **Hemolysis** – Tested in accordance with ASTM F756 and ISO 10993-4
- **Coagulation** – Tested in accordance with ASTM F2382
- **Particulate** – Tested in accordance with USP 788
- **Complement System** – Testing was performed in accordance with ISO 10993-4
- **Thrombogenicity Testing** – Testing was performed

Performance/Safety: A risk/hazard analysis was conducted according to EN ISO 14971 (Medical Devices-Application of Risk management to medical devices). Performance characteristics for this indication for use were identified which included a review of both ISO 10555-1 (Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements) and ISO 10555-2 (Sterile, single-use intravascular catheters – Part 2: Angiographic catheters). It was then determined that the performance of the Surefire® High Flow Angiographic Catheter is substantially equivalent to the performance and safety of the Angiodynamics Soft-Vu Angiographic Catheter. A battery of tests was performed according to protocols based on the requirements of recognized standards and was shown to meet the acceptance criteria that were determined to be applicable to the safety and efficacy of the device.

Additional Safety Information: Manufacturing controls include visual, functional, dimensional and sterility tests. Blood contacting materials were tested in accordance with

the tests recommended in the FDA General program Memorandum. Biocompatibility testing was conducted in accordance with International Standard ISO 10993, "Biological Evaluation of Medical Devices Part -1 Evaluation and testing".

Substantial Equivalence:

The Surefire® High Flow Angiographic Catheter is substantially equivalent in intended use, design, and technology/principles of operation to the predicate. Both devices share the same Indications for Use. Both devices have a 5F outer diameter. The tip of both the predicate and the proposed device have an equivalent geometry. Both products are designed to be compatible with 0.038" guidewires. The Microcatheter is substantially equivalent to the Angiodynamics Soft-Vu Angiographic Catheter, cleared under K112452. Differences between the devices do not raise any issues of safety or effectiveness.

Test data provided in bench tests demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the predicate device.

Submitter Information:

Prepared by: Mario Arbesu
Director, Quality Assurance and Regulatory Affairs

Prepared for: Surefire Medical, Inc.
12415 SW 136 Avenue
Unit 3
Miami, FL 33186

Date: July 16, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2013

Surefire Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K122506
Trade/Device Name: Surefire® High Flow Angiographic Catheter
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 8, 2012
Received: August 16, 2012

Dear Mr. Job:

This letter corrects our substantially equivalent letter of September 20, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Surefire® High Flow Angiographic Catheter

Indication for Use: The SUREFIRE HIGH FLOW ANGIOGRAPHIC CATHETER is intended for use where angiographic diagnosis is indicated.

Prescription Use ___X___ AND/OR Over-The-counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122506